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Charles W. Ashbrook/Assistant General Counsel
WARNER-LAMBERT COMPANY
Pharmaceutical Research Division
2800 Plymouth Road
Ann Arbor, MI 48105

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,962,098

NOTICE OF FINAL DETERMINATION

An application for extension of the patent term of U.S. Patent No. 4,962,098 under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on November 21, 1996. The application was filed by Warner-Lambert Company, the patent owner of record. Extension is sought based upon the premarket review under § 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) of a human drug product known by the tradename ESTROSTEP® having the active ingredients norethindrone acetate and ethinyl estradiol. ESTROSTEP® was approved for commercial use and sale by the Food and Drug Administration (FDA) on October 9, 1996.

A determination has been made that U.S. Patent No. 4,962,098 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of ESTROSTEP®.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

FDA's official records indicate that norethindrone acetate and ethinyl estradiol were previously approved for commercial marketing or use prior to the approval of ESTROSTEP®. In a letter dated July 8, 1997, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd. 894 F. 2d 392 (Fed. Cir. 1990). For example, LOESTRIN, manufactured by Parke Davis, contains both of the same active ingredients, ethinyl estradiol and norethindrone acetate (see attachment). In addition, both active ingredients have been approved in other products separately. For example, ESTINYL, manufactured by Schering, contains ethinyl estradiol, and AYGESTIN (Wyeth

Ayerst) and NORLUTATE (Parke Davis), both contain norethindrone acetate (see attachment).

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 4,962,098 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a human drug product means the active ingredient of the new drug product. The active ingredients in the approved product are norethindrone acetate and ethinyl estradiol. As noted in the above FDA letter and shown in the attachment thereto (pages 3-129 and 130 of the Prescription Drug Product List of the Approved Drug Products with Therapeutic Equivalence Evaluations, 17th Edition, 1997), the active ingredients have been approved for commercial marketing and use prior to the approval of the applicant's product, together as well as individually. Furthermore, the prior approval of the active ingredients in the product LOESTRIN, for example, by the Food and Drug Administration was under section 505 of the FFDCA, the same provision of law under which regulatory review of the product ESTROSTEP® occurred. Applying the definition of "product" provided in section 156(f) to the extension requirement of § 156(a)(5)(A), the approval of ESTROSTEP® does not qualify as the first permitted marketing or use of either active ingredient thereof. Since the approval of ESTROSTEP® was not the first permitted marketing or use of either of the active ingredients thereof, norethindrone acetate and ethinyl estradiol, the patent is not eligible for patent term extension based upon the regulatory review of ESTROSTEP®. See In re Alcon Laboratories, Inc., 13 USP2d 1115 (Comm'r Pats. 1989); In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990).

In view of the above, the term of U.S. Patent No. 4,962,098 is not eligible for extension under 35 U.S.C. § 156 based upon the approval of the product ESTROSTEP® and the application for patent term extension, filed November 21, 1996, is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: ESTROSTEP®
FDA Docket No.: 97E-0045

TABLE I

Number (percent) of patients with at least one day of spotting, breakthrough bleeding, or both during pill taking period, by week within cycle.

Formulation	Week 1 (Days 1-7)	Week 2 (Days 8-14)	Week 3 (Days 15-21)
Loestrin 1/20	36 (7.8)	150 (32.7)	119 (25.9)
Loestrin 1.5/30	29 (5.9)	71 (14.4)	88 (17.8)
Norlestrin 1/50	20 (4.5)	60 (13.6)	77 (17.5)
Estrostep	24 (5.2)	54 (11.6)	59 (12.7)